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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

KURIN, INC.,

Plaintiff,

v.

ICU MEDICAL, INC. AND VASCULAR INTEGRITY, LLC,

Defendants.

Case No. 8:24-cv-564

COMPLAINT FOR:

(1) FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125)
(2) FALSE ADVERTISING IN VIOLATION OF CAL. BUS. & PROF. CODE § 17500 ET SEQ.
(3) UNLAWFUL TRADE PRACTICE IN VIOLATION OF CAL. BUS. & PROF. CODE § 17200 ET SEQ. BY DEFENDANTS
(4) UNFAIR COMPETITION UNDER COMMON LAW

DEMAND FOR JURY TRIAL

Plaintiff Kurin, Inc. ("Kurin" or "Plaintiff"), for its Complaint against Defendants ICU Medical, Inc. ("ICU") and Vascular Integrity, LLC ("VI") (collectively, "Defendants"), alleges as follows:

OVERVIEW OF THE ACTION

Overview of Kurin

1. Kurin® is a privately held, certified minority owned business dedicated to engineering better healthcare through innovative, cost-effective, clinician-approved technologies. Kurin is focusing its depth of experience in medical device engineering, marketing, sales and service, on the persistent and costly fallout of false positive blood cultures.

2. Blood culture contamination (BCC) that causes false positive results has consequences. Antibiotic misuse has led to life-threatening multi-drug resistant super bugs. Contaminated blood cultures put patients at higher risk of in-hospital mortality, contribute to unnecessary antibiotic use and resistance, increase length of stay and associated healthcare-acquired conditions, and create delays in proper treatment.

3. Kurin is a proven innovator and leader in blood culture collection technologies that reduce BCC that causes false positive results. Since its founding in 2015, Kurin has developed some of the most advanced and effective blood culture collection technologies in the world, including the Kurin Lock® and the more recent Kurin Jet™.

4. Kurin is perhaps best known for its flagship product, the Kurin Lock®. The Kurin Lock® is a blood culture collection device cleared by U.S. Food and Drug Administration ("FDA") for reducing blood culture contaminations. In December 2016, the FDA issued its first clearance for the Kurin Lock® as a blood culture collection device for reducing blood culture contaminations. Kurin received three subsequent FDA clearances for the Kurin Lock®, including in April 2023, FDA clearance (K220677) for indications of use that include this statement: "The Kurin Blood Collection System is for use as a blood collection system and its Kurin Lock

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allows the initial specimen of blood from the patient to be sidelined prior to the collection of the test sample to reduce the frequency of blood culture contamination compared to blood cultures drawn using standard practice without the Kurin Lock."

5. The Kurin Lock® has frequently been the subject of clinical studies. There are three peer-reviewed journal articles and over a dozen posters, abstracts, and presentations at various clinical conferences over the years. Kurin Lock has been clinically presented at many clinical conferences, such as the American Professionals of Infection Control, The Emergency Nurses Association, The National Association of Clinical Nurses Specialists, and a variety of Clinical Laboratory conferences.

6. Since FDA clearance, the Kurin Lock® product family has been helping save lives and reduce healthcare costs by reducing contaminated blood cultures by more than 80% and driving hospital rates below the recommended 1% target.

7. With agile development capabilities and intense customer focus, the Kurin Lock® and the new Kurin Jet™ have quickly gained caregiver acceptance, been proven to sideline skin contaminants during blood culture collection, and have become the market leading solution for blood culture collection best practice.

8. The Kurin Lock® has been used millions of times. It has revolutionized blood culture collection, reducing blood culture contaminations, changing countless lives, and saving millions in hospital costs in the process.

Overview of Defendants' False and Misleading Claims

9. Defendant VI is a privately-owned start-up company. VI purports to have developed its own VI Velocity Reduction Technology™ that allows for blood diversion, allegedly helping minimize the risk of false positive blood cultures.

10. In direct competition with the Kurin Lock, VI makes and offers the VI ByPass Syringe™ Blue, the VI ByPass Syringe™ Red, and the VI ByPass Syringe™ Clear, and associated VI Velocity Reduction Technology™ (collectively and individually, the "ByPass Syringe™" or "VI Syringe"). VI advertises and promotes the VI Syringe on its website at **vascularintegrity.com** and through brochures and

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other written materials. VI relies on the extensive resources, reach, access and distribution network of Defendant ICU to distribute the VI Syringe in the marketplace. In addition, VI's association with ICU provides for its customers a misplaced sense of credibility supporting these claims.

11. On information and belief, ICU is the sole and exclusive distributor of the VI Syringe. On information and belief, ICU is a publicly traded company on the NASDAQ with a market cap of about $2.5 billion USD and annual revenues of about $2.3 billion USD. ICU advertises and sells the VI Syringe on its website **icumed.com** and provides a link to VI's website **vascularintegrity.com**.

12. On information and belief, ICU and VI are closely related, as VI's VP of Sales and Marketing, Jeff Lundy, has an ICU email address at jeff.lundy@icumed.com, and VI's VP of Clinical Affairs, Chonna Bartholomew, has an ICU email address at chonna.bartholomew@icumed.com, according to VI's contact webpage, a true and correct copy of which is attached as **Exhibit 1**. ICU is repeatedly and prominently identified in VI's advertisements and other promotional materials for the VI Syringe.

13. Kurin brings this action to put a stop to Defendants' commercial misinformation campaign that is spreading false and misleading clinical performance claims regarding Defendants' VI Syringe that deceive the medical community and endanger patient safety. Defendants have disseminated false and misleading clinical performance claims for their VI Syringe to deceive and mislead the medical community.

14. Defendants' false advertising includes deceptive claims regarding the VI Syringe, false and misleading statements based on an *in vitro* study, false and misleading statements regarding FDA clearance of the VI Syringe, Defendants' statements regarding the VI Syringe, and false and misleading statements regarding performance results of the VI Syringe, all of which harm Kurin.

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15. Defendants' false and misleading performance claims all purportedly rely on a non-peer reviewed study by VI itself (the "VI Study", as further described herein). But the VI Study does not and cannot support those claims, including because it has numerous fundamental limitations and defects, as well as unsubstantiated conclusions.

16. Even though Kurin's products are supported by far more rigorous clinical studies and far more robust data, Defendants' efforts are designed to mislead physicians, payors, investors, and other stakeholders, including government agencies, health systems, key opinion leaders ("KOLs"), advocacy groups, medical societies, and task forces, into believing that the VI Syringe is superior (or at least equivalent) to the Kurin's products, and to misappropriate hard-earned market share from Kurin.

17. On information and belief, Kurin is already absorbing the impact of Defendants' misinformation, with investors, media, and physicians accepting Defendants' touted performance of the VI Syringe at face value rather than understanding that those claims are not established by the VI Study or any other study.

18. Kurin's harm from Defendants' false advertising and deceptive and unfair business practices includes, among other harms, loss of market share, diminished reputation and goodwill, and loss of revenue. Moreover, because Defendants' statements have deceived the medical community about the qualities, characteristics and performance of the VI Syringe relative to the Kurin Lock®, Kurin must now expend resources correcting misperceptions in the marketplace, causing Kurin further harm.

19. Defendants' false advertising claims also pose a threat to patient health. Defendants are falsely and misleadingly representing important performance metrics about the VI Syringe. The medical community is being deceived about what VI Syringe's established performance is, and will be, in the intended use population,

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including how likely the test is to give false positive results (i.e., indicating bloodstream infection), thus putting patient safety at risk and increasing healthcare costs.

20. Having spent years and countless resources, including millions of dollars developing passive blood culture collection devices cleared by the FDA for reducing blood culture contaminations, Kurin cannot stand idly by while Defendants willfully spread false and misleading information about Defendants' unproven VI Syringe to clinicians, payors, and the medical community more broadly. Defendants' actions not only harm Kurin, but also threaten patients. Kurin thus brings this action for relief, including to enjoin Defendants from making false and misleading statements about the nature, quality, characteristics and performance of the VI Syringe. States.

THE PARTIES

21. Kurin is a corporation organized and existing under the laws of the state of Delaware, with a place of business at 10840 Thornmint Road, Suite 111, San Diego, California 92127.

22. On information and belief, ICU is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 951 Calle Amanecer, San Clemente, California 92673.

23. On information and belief, VI is a limited liability company organized and existing under the laws of the State of California having a principal place of business at 21571 Surveyor Circle, Huntington Beach, CA 92646.

JURISDICTION AND VENUE

24. This Court has jurisdiction over the subject matter of this action, without regard to the amount in controversy, as this action arises under the Lanham Act, 15 U.S.C. § 1125(a) *et seq.*, and this Court has subject matter jurisdiction over the Lanham Act claim and related unfair competition claims pursuant to and 28 U.S.C. §§ 1331 and 1338(b). This Court also has supplemental jurisdiction over Kurin's

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state-law claims pursuant to 28 U.S.C. § 1367(a) because they are related to Kurin's Lanham Act claim and form part of the same cases or controversies.

25. This Court has personal jurisdiction over ICU at least because it has a principal place of business in this District.

26. This Court has personal jurisdiction over VI at least because it has a principal place of business in this District and is a limited liability company formed in California.

27. Defendants are also subject to this Court's personal jurisdiction because Defendants make false and misleading descriptions and representations of fact in commercial advertising and promotion of goods and services, including their VI Syringewithin the State of California and this District. Defendants also conduct deceptive and unfair trade practices in the State of California and this District by, among other things, making false and misleading descriptions and representations of fact in commercial advertising and promotion of goods and services that will be used in California and this District.

28. Venue is proper in this District under 28 U.S.C. §§ 1391 at least because each of ICU and VI has a principal place of business in this District, and thus resides in this District.

FACTUAL BACKGROUND

KURIN AND THE KURIN LOCK® FAMILY OF PRODUCTS

29. Founded in 2015, Kurin is an established leader in the field of blood culture collection sets whose mission includes reducing contaminated blood cultures and the suffering and increased healthcare costs caused by contaminated blood cultures. Since its founding, Kurin has invested substantial resources in the research, development, and advancement of innovative new tools and methods for blood culture collection sets. Kurin's efforts have given rise to novel and proprietary blood culture collection sets that are available to healthcare providers and their patients to assist with life-saving decisions based on blood culture testing.

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30. Through its years of groundbreaking work, Kurin has developed and commercialized some of the most impactful blood culture collection sets ever made available to healthcare providers and their patients, including the Kurin Lock® and the new Kurin Jet™. Kurin's blood culture collection sets help doctors and patients get the answers they need to make more informed decisions based on blood culture testing.

31. Kurin presently employs more than 70 full-time employees, all of whom are based in the United States. Kurin has invested substantial amounts of its revenues in the development and commercialization of its Kurin Lock® product family that implement its innovations for reducing contaminated blood cultures.

32. The importance of effective, widely-available blood culture collection sets that reduce contaminated blood cultures cannot be understated. Approximately 1/3 of all positive blood cultures are false positive blood cultures. Research suggests that approximately 90% of all blood culture tests have negative results.[1] This means that for every 1000 blood draws, about 100 patients receive a positive result. But, well-established false positive blood culture rates[2] tell us that about 30 of the patients who test positive do not have a bloodstream infection.

33. Bloodstream infection (BSI) is a leading cause of death in the U.S., with a mortality rate up to 48%.[3] A blood culture test is the gold standard for BSI diagnosis. Of positive tests, about 1/3 are false-positives caused by blood culture specimen contamination. Positive results—true or false—likely prompt antimicrobial therapy and increase length of hospital stay. Antimicrobial misuse has led to 2.8M+ antibiotic-resistant infections and greater than 35,000 deaths annually.[4]

34. Blood culture contamination (BCC) that causes false positive results has consequences. Antibiotic misuse has led to life-threatening multi-drug resistant super

[1] Zwang O, Albert RK. J Hosp Med. 2006 Sep;1(5):272-6.
[2] Garcia RA et al. Am J Infect Control. 2015 Nov 1;43(11):1222-37.
[3] McNamara JF et al. J Infect. 2018 Jul;77(1):1-8.
[4] The Centers for Disease Control and Prevention. 2019 AR Threats Report.

bugs. Contaminated blood cultures put patients at higher risk of in-hospital mortality[5], contribute to unnecessary antibiotic use and resistance, increase length of stay and associated healthcare-acquired conditions, and create delays in proper treatment.[6] The cost of a false-positive blood culture is estimated at $4,000-$10,000[7], negatively impacting hospital financial performance.

35. A new CMS law[8] will penalize hospitals that are not demonstrating facility-wide antibiotic stewardship best practice, including avoiding unnecessary antibiotic use. In addition, CMS has said that BCCs are an important metric for Hospital Onset Bacteremia. CMS has recently published on the importance of accurate blood culture results and has asked for voluntary reporting as a first step in the process, similar to the process that CMS used for Central Line Bloodstream Infections (CLABSIs), which started with voluntary reporting and ended with financial penalties for poor performers.

36. Today, experts suggest that overall institutional blood culture contamination (BCC) rates of less than 1% are now achievable, and therefore, should become the universal performance benchmark.[9] However, hospitals still measure themselves against the outdated Clinical Microbiology Laboratories (CML) standard that said BCC rates should not exceed 3%, based on a 1998 Q Probe survey.[10] Even when hospitals achieve the 3% rate, approximately one-third of their positive results are inaccurate. That means, about 1/3 of all patients who receive a positive blood

[5] Davis et al. Open Forum Infectious Diseases, 6 (2): S676. October 2019.
[6] Doern GV et al. Clin Microbiol Rev. 2019 Oct 30;33(1).
[7] Garcia RA et al. Am J Infect Control. 2015 Nov 1;43(11):1222-37; Davis et al. Open Forum Infectious Diseases, 6 (2): S676. October 2019; Rupp ME, Cavalieri RJ, Marolf C, Lyden E. Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. Clin Infect Dis. 2017 Jul 15;65(2):201-205; Skoglund E, Dempsey C, Chen H, and Garey KW. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: A cost-benefit analysis. J. Clin. Microbiol. Posted Online 24 October 2018.
[8] Federal Register 84 FR 51732. Final rule 42 C.F.R § 482.42 to amends the Conditions of Participation. Sept. 30, 2019.
[9] Doern GV et al. A Clin Microbiol Rev. 2019 Oct 30;33(1).
[10] Schifman RB et al. Arch Pathol Lab Med 1998 Mar;122(3):216-221; Bekeris LG et al. Arch Pathol Lab Med 2005;129:1222-5.

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culture result—and for whom antibiotic treatment is initiated—are put at risk unnecessarily.

37. Skin contaminants are the most common blood culture contamination source. Roughly 20% of the microbes present in skin reside deep in the dermis layer and may be drawn into blood specimens.[11] Without a means to eliminate the contaminants from the skin, hospitals accept high rates of seemingly unavoidable false positives blood cultures. "It is currently accepted that most organisms identified as contaminants in BCs originate from the skin of the patient."[12] Blood culture contamination represents an ongoing source of frustration for clinicians, microbiologists, and hospital administrators, negatively impacting patient experience and unnecessarily adding to the cost of care.

38. There are several points of potential "touch contamination" whereby microbes from the environment, collection devices, or the clinician's hands may introduce contaminants into the blood culture specimen. Contamination may occur during site preparation for venipuncture or catheter insertion, during collection set assembly, or when collection bottles are not properly disinfected. Indeed, several points of potential contamination exist during routine blood culture collection, including preparation (when a sterile field is breached), collection set assembly (from bacteria on clinicians hands or surfaces), venipuncture (when skin contaminants are drawn into the specimen), and sample handling (when bacteria comes to reside on culture bottles) (the "Four Points of Contamination").

39. The most common source of contaminants are the organisms, existing as skin flora, that appear in blood culture specimens. These contaminants are generally coagulase-negative staphylococci (CoNS), Corynebacterium species,

[11] Garcia RA, Spitzer ED, Beaudry J, et al. Multidisciplinary team review of best practices for collection and handling of blood cultures to determine effective interventions for increasing the yield of true-positive bacteremia, reducing contamination, and eliminating false-positive central line-associated bloodstream infections. Am J Infect Control. 2015 Nov 1;43(11):1222-37.

[12] *Id.*

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Bacillus species other than anthracis, and P. acnes. Unfortunately, skin antisepsis alone cannot eliminate these contaminants as they may reside below the skin's surface.

40. In part, contamination can be reduced by limiting the possible points of contamination in the blood culture collection processes. For example, the additional steps involved in drawing a blood culture specimen using a syringe increases the risk of contamination by 300%.

41. The false positive blood culture costs to hospitals are high. Likewise, the unnecessary treatment of a suspected bloodstream infection poses serious clinical risk for patients. The financial cost of false positive blood cultures include: Healthcare insurers no longer reimburse hospital-acquired infections; the cost of a false-positive blood culture is estimated at about $4,000-$10,000;[13] with 1/3 of all positive blood culture results being inaccurate, the average hospital spends more than $1 million dollars on unnecessary treatment of non-existent bloodstream infections; each year, U.S. hospitals waste several billion dollars related to more than one million false-positive results; and non-compliance with CMS rule 42 C.F.R § 482.42 for the avoidance of antibiotic misuse will results in reimbursement penalties.

42. The clinical cost of false positive blood cultures include: in-hospital mortality increases for patients with false positive blood cultures;[14] extended hospital stays increase the risk of hospital-acquired infections and adverse events;[15]

[13] Garcia RA, Spitzer ED, Beaudry J, et al. Multidisciplinary team review of best practices for collection and handling of blood cultures to determine effective interventions for increasing the yield of true-positive bacteremia, reducing contamination, and eliminating false-positive central line-associated bloodstream infections. Am J Infect Control. 2015 Nov 1;43(11):1222-37; Davis KA et al. Open Forum Infectious Diseases, 6 (2): S676. October 2019; Rupp ME, Cavalieri RJ, Marolf C, Lyden E. Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. Clin Infect Dis. 2017 Jul 15;65(2):201-205; Skoglund E, Dempsey C, Chen H, and Garey KW. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: A cost-benefit analysis. J. Clin. Microbiol. Posted Online 24 October 2018.

[14] Davis KA et al. Open Forum Infectious Diseases, 6 (2): S676. October 2019.

[15] *Id.*

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unnecessary antibiotics increase the risk of allergic reactions and drug interactions; the overuse of antibiotics lessens the efficacy of future treatment, leaving patients vulnerable to multidrug-resistant superbugs; delays in proper diagnosis and treatment; and the discomfort, inconvenience, and anxiety caused by unnecessary treatment lowers patient satisfaction scores. For example, when a patient is misdiagnosed because of a BCC, the original problem that forced them to the Emergency Department is not being treated, so the patient is at risk for those symptoms to worsen while they treat a nonexistent infection and an untreated condition may potentially lead to death.

43. Three factors influence the efficacy of technology designed to reduce blood culture contamination (BCC) rates.[16] First, as to sample definition – Does it include all cultures drawn over a period or only those drawn WITH the device? Second as to method inclusion – Does it account for cultures drawn by all methods (venipuncture, syringe draws, and peripheral IV catheter)? Third, as to environmental control – Was the use of the technology heavily policed or were clinicians acting autonomously in using the device?

44. Kurin Lock® blood culture collection sets passively sideline the initial 0.15ml of blood, which may contain contaminants from the patient's own skin, ensuring that the best possible blood specimen reaches the collection bottles. Passive technology complements clinician workflow, ensuring high levels of compliance and sustained outcomes. Studies show that best practice compliance combined with Kurin collection can reduce contaminated cultures by more than 80% and drive hospital rates below the recommended 1% target. When Kurin is consistently used, hospitals significantly reduce blood culture contamination (BCC) rates below the 1% target and achieve substantial cost savings.[17]

[16] https://www.kurin.com/studies/
[17] https://www.kurin.com/studies/

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45. Both effective and simple to use, Kurin's products have been widely adopted, having been used millions of times by healthcare providers worldwide.

DEFENDANTS' FALSE ADVERTISING, DECEPTIVE AND UNLAWFUL TRADE PRACTICES, AND UNFAIR COMPETITION

Overview of Defendants' False and Misleading Claims

46. VI promotes the VI Syringe as shown in **Exhibit 2**, which is a true and correct copy of VI's webpage (https://vascularintegrity.com/). As shown in Exhibit 2, for example, VI states that its VI Syringe "reduce[s] risk of false positive blood cultures", it is "evaluated and endorsed by ANTT to reduce contamination and ensure best practice" (ANTT is further described in **Exhibit 3**), and "decrease[s] device-related hemolysis." On information and belief, VI has not submitted data to the FDA about its VI Syringe and the FDA has not cleared VI to make these statements about the VI Syringe.

47. ICU is a distributor of the VI Syringe as shown in **Exhibit 4**, which is a true and correct copy of ICU's webpage (https://www.icumed.com/products/infusion-therapy/vascular-access/blood-collection/blood-diversion/vi-bypass-syringe/), through which ICU promotes linking to the VI website regarding the VI Syringe. ICU thus promotes the VI Syringe. VI also promotes ICU as the distributor of the VI Syringe. For example, VI's VP of Clinical Affairs, Chonna Bartholomew, promotes ICU as the distributor of the VI Syringe on a LinkedIn page, a true and correct copy of which is attached as **Exhibit 5**. As another example, a regional manager at Smiths Medical, which was acquired by ICU, further promoted ICU as the distributor of the VI Syringe with the tags #icumedical and #blooddiversion on a LinkedIn page, a true and correct copy of which is attached as **Exhibit 6**. Another LinkedIn page, a true and correct copy of which is attached as **Exhibit 7**, identities the regional manager at ICU Medical.

48. Defendants have engaged in a campaign to disseminate false and misleading clinical performance claims for their VI Syringe. Defendants'

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misinformation, such as in Exhibit 2, and further promotional materials described below, seeks to convince the medical community that Defendants' VI Syringe has material qualities and characteristics that it does not, and therefore Defendants mislead the medical community that the VI Syringe should be ordered over other products, including the Kurin Lock® product family.

49. Defendants' false and misleading claims include statements about critical clinical performance metrics regarding their VI Syringe that physicians, payors, investors, and other stakeholders, including government agencies, health systems, KOLs, advocacy groups, medical societies, and task forces, look to in order to ascertain how the product will actually perform in the intended population in real-world clinical settings. The studies on which Defendants rely to support these claims are (a) based on outdated data, (b) based on data for a substantially different product, (c) not conducted by third parties, (d) not available for peer-review or public scrutiny, (e) methodologically defective, and (f) cannot establish Defendants' marketing claims regarding the VI Syringe.

50. Below, Kurin addresses each of Defendants' false and misleading claims, referred to below as the 99.9% Claim, the FDA Clearance Claim, the Patented Claim, the VI Study Claim, the Aseptic/Sterile Field Claim, BCC/CLABSI Reduction Claim, and the Hemolysis Reduction Claim.

Defendants' False and Misleading 99.9% Claim

51. As shown in **Exhibit 8** to this complaint, which is a true and correct copy of a VI Syringe brochure (https://vascularintegrity.com/wp-content/uploads/2021/02/VI-ByPass-BCC-brochure.pdf), VI claims that the VI Syringe "Improv[es] sample quality by removing over 99.9% of contaminates" (the "**99.9% Claim**"). As alleged support that that claim, in Exhibit 8, VI refers to "Vascular Integrity FDA 510K documentation on file." A Google search for "510k vascular integrity" yields a list of results that include Exhibit 8, a true and correct copy of such search results being listed in **Exhibit 9**. On information and belief, VI

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made the VI Syringe brochure (Exhibit 8) available on VI's website by about February 2021 (as indicated in Exhibit 9), in which VI claimed that "Vascular Integrity FDA 510K documentation on file" supported the 99.9% Claim.

52. On information and belief, on June 10, 2022, VI made a Freedom of Information Act (FOIA) request bearing control number 2022-4298 for FDA 510K documentation, where VI stated: "The previous owner of vascular logistics (Dr. Brannon) had exchanged letters with the FDA regarding not needing to file for a new 510k number. In those letters, Dr. Brannon used data to prove the products were similar. We are trying to obtain that data and the letters that correspond with them. the 510K numbers are K965030, K960047, and K960049." On information and belief, on or before June 10, 2022, VI did not have FDA 510K documentation for the 99.9% Claim when VI made the VI Syringe brochure available on VI's website by about February 2021. A true and correct copy of a FOIA request log, among a list of other logged FOIA requests, is attached as **Exhibit 10**, which can be found in a Google search result, a true and correct copy of which is attached is **Exhibit 11**.

53. Although Exhibit 8 also refers to "Toxikon Clinical Lab Invitro testing Diversion study, Data on file" (the "Toxikon Study") for the claim that the VI Syringe "Provides waste/contaminate separation from whole blood," Exhibit 8 does not reference the Toxikon Study for the 99.9% Claim. The Toxikon Study is not available on VI's website. On information and belief, the Toxikon Study belies and/or does not support the 99.9% Claim.

54. Defendants' 99.9% Claim seeks to convince the medical community that Defendants' VI Syringe has material qualities and characteristics that it does not, and therefore Defendants mislead the medical community that the VI Syringe should be ordered over other products, including the Kurin Lock® product family.

55. On information and belief, as described above and further below, the 99.9% Claim by Defendants is false and misleading.

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Defendants' False and Misleading FDA Clearance Claim

56. On information and belief, as further described below, Defendants have falsely and misleadingly claimed that the FDA has cleared the 99.9% Claim (and other statements as further described herein). For example, Exhibit 8 refers to "Vascular Integrity FDA 510K documentation on file."

57. Moreover, on information and belief, as further described below, in addition to VI falsely and misleadingly claiming FDA clearance of the 99.9% Claim (or other statements as further described herein), Defendants have falsely and misleadingly marketed the VI Syringe as if it were the Brannon PortSyringe so that the Class II device FDA clearance of the Brannon PortSyringe is somehow applicable to the VI Syringe, or falsely and misleadingly claimed to the FDA that VI is the specification developer and contract manufacturer of the Brannon PortSyringe (collectively, the "**FDA Clearance Claim**").

58. On information and belief, VI never applied for FDA clearance of the VI Syringe for blood culture collection, and rather, VI just submitted a company name change to the FDA for a different syringe, the Brannon PortSyringe, as further described below.

59. Although the Brannon PortSyringe has FDA clearance, that clearance was for a different set of indications, namely a two-step approach to collecting blood through a catheter for lab tests, and not for blood cultures. In the catheter application of the Brannon PortSyringe, diversion is used to pull out any solution that is filling the catheter (drugs or flush) so that a subsequent all blood sample can be taken. Those indications for use are substantially different from how Defendants now promote the VI Syringe for BCC reduction and other indications for use, as described further below.

60. Further, as shown in **Exhibit 12**, which is a true and correct copy of an FDA webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?rid=

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270213), VI has an FDA Establishment Registration & Device Listing under FEI number 3016965628.

61. Under FEI number 3016965628, as shown in **Exhibit 13**, which is a true and correct copy of a FDA webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm), VI has an FDA Establishment Registration & Device Listing, that includes three listings, including the "Syringe, Piston – Syringe, Piston," the "Syringe, Piston – By-Pass Syringe- Luer Access," and the "Syringe, Piston – Syringe, Piston."

62. As to the "the "Syringe, Piston – By-Pass Syringe- Luer Access," as shown in **Exhibit 14**, which is a true and correct copy of an FDA webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?lid=683816&lpcd=FMF), the FDA webpage provides a link to Premarket Submission Number K960049.

63. The FDA webpage for Premarket Submission Number K960049, as shown in **Exhibit 15**, which is a true and correct copy of an FDA webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K960049), refers to an FDA submission in 1996 for a "BRANNON PORTSYRINGE" and provides a link to a "Summary." On information and belief, VI did not exist in 1996 and does not develop or manufacture the BRANNON PORTSYRINGE.

64. The "Summary" for Premarket Submission Number K960049, submitted February 1996 and cleared in May of 1996, identifies James K. Brannon, M.D. as recipient, as shown in **Exhibit 16**, which is a true and correct copy of an FDA webpage (https://www.accessdata.fda.gov/cdrh_docs/pdf/K960049.pdf). The Premarket Submission Number K960049 (Exhibit 16) refers to the Brannon PortSyringe, rather than any VI Syringe, and does not refer to any clinical data for any removal of blood contaminates.

65. The "Summary" for Premarket Submission Number K965030, dated December 1996, identifies James K. Brannon, M.D. of VASCULAR LOGICS, INC. as recipient, as shown in **Exhibit 17**, which is a true and correct copy of an FDA

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webpage (https://www.accessdata.fda.gov/cdrh_docs/pdf/K965030.pdf). The Premarket Submission Number K965030 refers to the "Brannon Arterio-Venous PortSyringe, A-VPS," and represents to the FDA that "the A-VPS is identical to the Brannon PortSyringe K960049, except the A-VPS includes a centrally disposed inner cannula within its barrel." The Premarket Submission Number K965030 (Exhibit 17) refers to the A-VPS, rather than any VI Syringe, and does not refer to any clinical data for any removal of blood contaminates.

66. As shown in Exhibit 8, Exhibit 12, Exhibit 13, Exhibit 14, Exhibit 15, Exhibit 16, and Exhibit 17, VI substituted its name for VASCULAR LOGICS, INC. and Dr. James K. Brannon in the corresponding FDA records as the specification developer and contract manufacturer of the Brannon PortSyringe cleared by the FDA in the 1990s, rather than submitted for FDA clearance of the VI Syringe.

67. On information and belief, as described above and further below, the FDA Clearance Claim is false and misleading.

Defendants' False and Misleading Patented Claim

68. Contrary to the FDA Clearance Claim above, on information and belief, as further described below, VI has falsely and misleadingly claimed that the VI Syringe was and is a patentable innovation and substantially different from the Brannon PortSyringe that VI relied upon for the FDA Clearance Claim (the "**Patented Claim**").

69. As an initial matter, as shown in Exhibit 25 (Microbial Diversion study, further discussed below), for example, VI falsely claims that the VI Syringe is "patented." Moreover, VI previously falsely claimed that the VI Syringe is "patented" in a "Microbial Contaminate Diversion" paper, a true and correct copy of which is attached as **Exhibit 26**.

70. VI has filed a number of U.S. patent applications distinguishing the Brannon PortSyringe from the structure and functionality of the VI Syringe. For example, on May 9, 2019, VI filed U.S. provisional patent application number

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62/845,767 ("the '767 Provisional Application"), entitled "IMPROVED SYRINGE WITH CONDUIT AND CANNULA FOR BLOOD DRAWS AND MEDICINE DELIVERY TO PATIENTS." Attached as **Exhibit 18** is a true and correct copy of the '767 Provisional Application. In the '767 Provisional Application, paragraph [0030], VI distinguishes "a prior art syringe 100 of the type disclosed in U.S. Patent Nos. 5,147,329 and 6,013,037." Attached as **Exhibit 19** is a true and correct copy of U.S. Patent No. 5,147,329 ("the '329 Patent"). Attached as **Exhibit 20** is a true and correct copy of U.S. Patent No. 6,013,037 ("the '037 Patent"), which also refers to itself as a Continuation-in-part of application No. 08/797,091, which issued as U.S. Patent No. 5,873,841 ("the '841 Patent"). Attached as **Exhibit 21** is a true and correct copy of the '841 Patent. Each of the '329 Patent, the'037 Patent, and the '841 Patent identify James K. Brannon as the sole inventor and collectively, the '329 Patent, the'037 Patent, and the '841 Patent are referred to herein as "the Brannon Patents."

71. As shown in the '767 Provisional Application (Exhibit 18), VI distinguished the VI Syringe from the Brannon Patents, for example, by arguing at paragraph [0045] that "[t]he embodiments of the present invention serve to minimize contamination risks by using a closed vascular system." In the '767 Provisional Application (Exhibit 18), at paragraph [0003], for example, VI distinguished the Brannon Patents by arguing that "[u]nfortunately, the current syringes having cylindrical bodies and plunger assemblies suffer from drawbacks, including unsatisfactory (i) connector performance and adaptability; (ii) cannula position and attachment; (iii) plunger design; and (iv) related design features."

72. Nowhere does the '767 Provisional Application (Exhibit 18) provide any clinical data to support VI's claim at paragraph [0045] that "embodiments of the present invention serve to minimize contamination risks by using a closed vascular system."

73. On December 4, 2020, VI later converted the '767 Provisional Application (Exhibit 18) to non-provisional U.S. patent application number

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17/112,790 ("the '790 Nonprovisional Application"), a true and correct copy of which is attached as **Exhibit 22**. The '790 Nonprovisional Application (Exhibit 22) removes the references to the Brannon Patents that were in '767 Provisional Application (Exhibit 18).

74. On March 25, 2021, the '790 Nonprovisional Application (Exhibit 22) eventually published as U.S. Patent Application Publication 2021/0085230 ("the '230 Publication"), a true and correct copy of which is attached as **Exhibit 23**. Like the '790 Nonprovisional Application (Exhibit 22), the '230 Publication (Exhibit 23) removes the references to the Brannon Patents that were in '767 Provisional Application (Exhibit 18). On information and belief, VI removed the references to the Brannon Patents to avoid publicly distinguishing the Brannon Patents from the VI Syringe, while at the same time falsely and misleadingly claiming to the FDA and general public either that the VI Syringe has FDA clearance, when it does not, or that the VI Syringe is the Brannon PortSyringe, as was described above.

75. The Brannon PortSyringe is described as the commercial development of the Brannon Patents, as shown in **Exhibit 24**, which is a true and correct copy of a patent assignment from Vascular Logics, Inc. (*i.e.*, the aforementioned recipient of FDA clearance of the Brannon PortSyringe) to V.L. Manufacturing, LLC. Based on the assignment of Exhibit 24, as of 2001 all rights in the Brannon Patents were held by V.L. Manufacturing, LLC. On information and belief, VI never received any rights in the Brannon Patents or the Brannon PortSyringe from either Vascular Logics, Inc. or V.L. Manufacturing, LLC. Regardless, on information and belief, Vascular Logics, Inc. was terminated in 2000 and V.L. Manufacturing, LLC was terminated in 2006.

76. On information and belief, as described above and further below, the Patented Claim is false and misleading.

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Defendants' False and Misleading VI Study Claim

77. On information and belief, as further described below, Defendants have made numerous false and misleading claims about the VI Syringe that are allegedly substantiated by VI's own "Microbial Diversion study".

78. VI's website (Exhibit 1) says that the VI Syringes "Help Reduce Risk of False Positives" and further states that the "VI Velocity Reduction Technology™ allows for Blood Diversion, helping minimize the risk of false positive blood cultures," and refers to and links to "our microbial contaminate study," a true and correct copy if which is attached as **Exhibit 25** (https://vascularintegrity.com/wp-content/uploads/2023/10/bbc-02.pdf) (the "Microbial Diversion Study"). Exhibit 25 is cited for the Blood Culture contamination (BCC) reduction claim that "Without disinfection of the surface, under worst case scenario, a 2ml waste collection diverted 99% of contaminates." Exhibit 25 references "Contamination Challenge Study Data on File Vascular Integrity" that is not made publicly available for peer review or public scrutiny. Collectively, the "Contamination Challenge Study Data on File Vascular Integrity", Exhibit 25 and all references to or reliance on such materials, are referred to herein as the "**VI Study Claim**."

79. Exhibit 25 (Microbial Diversion Study) describes the VI Study conditions as "The method used in this study was the analysis of the blood collected via the VI ByPass syringe Chamber™ and the VI Velocity Reduction System™ into a vacuum tube and comparing it to the blood collected straight into the standard syringe after the inoculation protocol (as outlined) using standard mathematical calculations."

80. The VI Study, for example, as shown in Exhibit 25 (Microbial Diversion Study), was done in conditions that are inapposite to routine blood culture collection and which violate industry protocols for conducting performance studies. For example, as described in Exhibit 25 (Microbial Diversion Study): "Several test pilots were performed, and the following study proved to be the best study to demonstrate

the ByPass Blood Collection Technology: "Vitro-Skin covering a parafilm wrapped petri dish containing pooled whole human blood was contaminated with Staphylococcus aureus (ATCC-6538) and allowed to incubate under ambient conditions for a minimum of ten (10) minutes. The inoculated Vitro Skin was placed atop the blood source containing approximately 150 mL blood." The VI Study was not conducted under an FDA agreed upon test protocol nor performed under conditions that consider when a sterile field is breached, which is required by industry protocols in order to draw any conclusions from the test. The VI Study was not performed in conditions that consider conditions from bacteria on clinicians hands or surfaces. The VI Study was not performed in conditions that consider skin contaminants drawn into a respective specimen. The VI Study was not performed in conditions that consider when bacteria comes to reside on culture bottles. Stated differently, the VI Study conditions failed to test the at least Four Points of Contamination in violation of industry standards.

81. The sample size of the VI Study is entirely too small to reach its overstated conclusion. For example, Exhibit 25 (Microbial Diversion Study) states that "[n]ine (9) BPS test article devices" [i.e., VI Syringes] were used in the study with only 3 used in each sub-group of .5 mL, 1 mL, and 2 mL waste categories. With only three samples in each category, the reported reduction in contaminate diversion in each waste class was never 99%, let alone 99.9%. Even so, the sample size of the VI Study is exceedingly small, and the testing conditions fail to consider the Four Points of Contamination, which would have been challenged if peer reviewed or evaluated by the FDA. There are no reported scientifically valid studies establishing a causal relationship between use of the VI Syringe and Defendants' BCC reduction claims.

82. VI's website (Exhibit 1) also refers to and links to webpages for the VI ByPass Syringe™ Blue ("VI Syringe Blue"), the VI ByPass Syringe™ Red ("VI Syringe Red"), and the VI Syringe Clear.

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83. As to the VI Syringe Blue, VI makes the unsupported claim, as set forth in **Exhibit 27**, which is a true and correct copy of VI's webpage (https://vascularintegrity.com/vi-bypass-syringe-blue/), that "The conduit VI Sliding Fluid Seal™ provides waste / contaminate separation from whole blood, shown in our microbial contaminate study to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Blue webpage refers to Exhibit 25, the Microbial Diversion Study discussed above. The VI Syringe Blue webpage also links to a VI Syringe Blue brochure, a true and correct copy of which is attached as **Exhibit 28**, which claims that it is "Designed to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Blue brochure (Exhibit 28) also refers to "icumedical" as promoter of the VI Syringe Blue. Together, all of these materials perpetuate Defendants' false and misleading claims, including but not limited to their false and misleading 99.9% Claim and VI Study Claim.

84. As to the VI Syringe Red, VI makes the unsupported claim, as set forth in **Exhibit 29**, which is a true and correct copy of VI's webpage (https://vascularintegrity.com/vi-bypass-syringe-red/), that "The conduit VI Sliding Fluid Seal™ provides waste / contaminate separation from whole blood, shown in our microbial contaminate study to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Red webpage refers to the VI Study, as shown in Exhibit 25, the Microbial Diversion Study discussed above. But the VI Study is defective in multiple, materials ways and does not support Defendants' claims. The VI Syringe Red webpage also links to a VI Syringe Red brochure, a true and correct copy of which is attached as **Exhibit 30**, which claims that it is "Designed to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Red brochure (Exhibit 30) also refers to "icumedical" as promoter of the VI Syringe Red. Together, all of these materials perpetuate Defendants' false and misleading claims, including but not limited to their false and misleading 99.9% Claim and VI Study Claim.

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85. As to the VI Syringe Clear, VI makes the unsupported claim, as set forth in **Exhibit 31**, which is a true and correct copy of VI's webpage (https://vascularintegrity.com/vi-bypass-syringe-clear/), that "The conduit VI Sliding Fluid Seal™ provides waste / contaminate separation from whole blood, shown in our microbial contaminate study to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Clear webpage appears to refer to the VI Study, as shown in Exhibit 25, the Microbial Diversion Study discussed above. But the VI Study is defective in multiple, materials ways and does not support Defendants' claims. The VI Syringe Clear webpage also links to a VI Syringe Clear brochure, a true and correct copy of which is attached as **Exhibit 32**, which claims that it is "Designed to improve sample quality by removing over 99.9% of contaminates." The VI Syringe Clear brochure (Exhibit 32) also refers to "icumedical" as promoter of the VI Syringe Clear. Together, all of these materials perpetuate Defendants' false and misleading claims, including but not limited to their false and misleading 99.9% Claim and VI Study Claim.

86. As described above, the VI Study was conducted in conditions that are contrary to routine blood culture collection and industry standards for performance testing. Defendants' claims mislead clinicians payors, and others in the medical community that the VI Syringe removes "over 99.9% of contaminates" in actual routine blood culture collection.

87. On information and belief, as described above and further below, the VI Study Claim is false and misleading.

Defendants' False and Misleading Aseptic/Sterile Field Claim

88. As described above and further below, Defendants mislead clinicians payors, and others in the medical community that the VI Syringe includes a field that is free from bacteria or otherwise free from contamination (the "**Aseptic/Sterile Field Claim**").

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89. Defendants falsely claim that VI Syringe includes a "micro critical aseptic field" as shown in **Exhibit 33**, which is a true and correct copy of a screen shot of a video available from VI at https://vascularintegrity.com/videos/, a true of correct copy of which is attached as **Exhibit 34**. Defendants thus mislead clinicians payors, and others in the medical community that the VI Syringe includes a field that is free from bacteria or otherwise free from contamination. Such a claim is contrary to Defendants' own materials described above.

90. Defendants also falsely claim that VI Syringe includes a "micro sterile field" as shown in **Exhibit 35**, which is a true and correct copy of a screen shot of a video available from VI at https://vascularintegrity.com/videos/, a true of correct copy of which is attached as Exhibit 34. Defendants thus mislead clinicians payors, and others in the medical community that the VI Syringe includes a field that is free from bacteria or otherwise free from contamination. Such a claim is contrary to Defendants' own materials described above.

91. Defendants also falsely claim that VI Syringe includes a "micro critical aseptic field" as shown in **Exhibit 36**, which is a true and correct copy of a screen shot of a video available from VI at https://vascularintegrity.com/videos/, a true of correct copy of which is attached as Exhibit 34. Defendants thus mislead clinicians payors, and others in the medical community that the VI Syringe includes a field that is free from bacteria or otherwise free from contamination. Such a claim is contrary to Defendants' own materials described above.

92. On information and belief, as described above, the Aseptic/Sterile Field Claim is false and misleading.

Defendants' False and Misleading BCC/CLABSI Reduction Claim

93. As described above and further below, as shown in Exhibit 1, Defendants mislead clinicians payors, and others in the medical community that the VI Syringes "Help Reduce Risk of False Positives," including "VI Velocity Reduction Technology™ allows for Blood Diversion, helping minimize the risk of

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false positive blood cultures," and "Help Reduce CLABSI," including "Designed to avoid breaks in aseptic technique required in multi-step line procedures that may contribute to CLABSI rates" (the "**BCC/CLABSI Reduction Claim**"). "A central line-associated bloodstream infection (CLABSI) is a laboratory-confirmed bloodstream infection not related to an infection at another site that develops within 48 hours of central line placement."[18]

94. As shown in Exhibit 1, Defendants refer to the VI Study to support these claims (Exhibit 25).

95. In the context of the 99.9% Claim, the FDA Clearance Claim, the Patented Claim, the VI Study Claim, and the Aseptic/Sterile Field Claim, the BCC/CLABSI Reduction Claim is false and misleading, including but not limited to the VI Syringe performance being unsupported by clinical data, peer-reviewed data or FDA clearance.

96. Exhibit 1 also refers to "Supporting Evidence Fluid Diversion Study" and says "The purpose of this study is to validate Vascular Integrity's ByPass Syringe with Sliding fluid seal™ performs effectively in isolating waste collection contaminates (diversion) during fluid collection." Exhibit 1 links to a "Fluid Diversion Study," a true and correct copy of which is attached as **Exhibit 37**. The Fluid Diversion Study (Exhibit 37) does not support Defendants' BCC/CLABSI Reduction Claim, as the Fluid Diversion Study (Exhibit 37) merely allegedly tested "separation of normal saline and glucose through Vascular Integrity's VI Sliding Fluid Seal™" which does not emulate how real blood behaves and provides no measure of BCC/CLABSI reduction. Moreover, the Fluid Diversion Study (Exhibit 37) refers to a "Vascular Integrity 510K Avail upon request," which as described above, is part of Defendants' false and misleading FDA Clearance Claim.

[18] https://www.ncbi.nlm.nih.gov/books/NBK430891/#:~:text=A%20central%20line%2Dassociated%20bloodstream,hours%20of%20central%20line%20placement.

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Defendants' False and Misleading Hemolysis Reduction Claim

97. As described above and further below, as shown in Exhibit 1, Defendants mislead the public that the VI Syringes "Help Reduce Hemolysis," including the statement that the "VI Velocity Reduction Technology™ is designed to help decrease device-related hemolysis, as seen in our hemolysis study" (the "**Hemolysis Reduction Claim**").

98. As shown in Exhibit 1, Defendants refer and link to "our hemolysis study," a true and correct copy of which is attached as **Exhibit 38**. Just as other studies mentioned herein, the hemolysis study (Exhibit 38) by VI was not peer reviewed or authorized by the FDA. Despite this, VI concludes in its study (Exhibit 38) that the VI Syringe "is considered non-Hemolytic" based on ASTM F756 guidelines (i.e., hemolysis guidelines used by the FDA). Reference to this guideline suggests that the VI's hemolysis study (Exhibit 38) is in compliance with the FDA even though the hemolysis study (Exhibit 38) does not describe how its study complies with ASTM F756. The sample size of the hemolysis study (Exhibit 38) is also only three samples. Use of only three samples is simply insufficient to conclude that the VI Syringe "helps reduce hemolysis". Reduction is a relative term, a reduction in hemolysis claim must be a comparison with existing methods.

99. Yet, by referring to the study of the hemolysis study (Exhibit 38) in its marketing material to support the false claim that the VI Syringe reduces hemolysis, VI falsely misleads the public that VI is authorized to make these clinical claims.

100. In the context of the 99.9% Claim, the FDA Clearance Claim, the Patented Claim, the VI Study Claim, the Aseptic/Sterile Field Claim, and the BCC/CLABSI Reduction Claim, the Hemolysis Reduction Claim is false and misleading, including but not limited to the VI Syringe performance being unsupported by clinical data, peer-reviewed data or FDA clearance.

101. Collectively, the 99.9% Claim, the FDA Clearance Claim, the Patented Claim, the VI Study Claim, the Aseptic/Sterile Field Claim, BCC/CLABSI

Reduction Claim, and the Hemolysis Reduction Claim are herein referred to as the "**Defendants' False and Misleading Claims**."

Defendants' Willfully False and Misleading Claims

102. Before this Complaint was filed, Kurin contacted ICU regarding Defendants' false and misleading claims. Defendants removed certain website statements, but they either added a "Learn More" link to the above False and Misleading Claims to their websites (as seen in Exhibit 4), or continued to make the above False and Misleading Claims on their websites.

The Harms Caused by Defendants' False and Misleading Claims

103. Defendants' False and Misleading Claims have caused harms as further described below.

104. It is of critical importance that physicians, patients, payors, investors, and other stakeholders, including government agencies, health systems, KOLs, advocacy groups, medical societies, and task forces, are not misled or deceived about the true clinical performance of a blood culture collection device like the VI Syringe. Particularly when it comes to new tests, physicians, payors, and other stakeholders rely on performance claims by diagnostic companies when deciding whether and which test to order for their patients (or which to cover, in the case of insurance). Physicians must be truthfully informed about the rate at which a test yields false positives in the real-world screening population so that they can properly care for and advise their patients.

105. A patient who unknowingly has received a false positive result may undergo an unnecessary regimen of antibiotics, which will waste time and resources and unnecessarily expose the patient to potential complications from the antibiotics. Either way, false positive results—arising for instance from false and misleading performance claims that mask a device's true performance— put patient health and safety at risk.

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106. Ensuring physicians, patients, payors, investors, and other stakeholders, including government agencies, health systems, KOLs, advocacy groups, medical societies, and task forces, are truthfully informed about test performance is thus a highly serious matter. It requires that companies act scrupulously and transparently when conducting scientific research, when publishing results of that research, and when discussing their data with the scientific community at large (*e.g.*, by acknowledging limitations and deviations from prior study approaches). It also demands that companies act responsibly by accurately promoting their tests with clinical performance claims that reflect the patient population in which the test will be used, and take steps to ensure that their study data (including any limitations they may have) are accurately understood so as to avoid unwarranted, unsubstantiated, or over-stated conclusions being drawn. Defendants have not acted in accordance with these principles, to Kurin's and the public's detriment.

107. As was discussed above regarding the FDA Clearance Claim, for example, Defendants' marketing claims are unsupported and unsupportable.

108. All of Defendants' marketing claims regarding the VI Syringe performance are purportedly based on a single unpublished study—the VI Study. However, because of how it was designed and conducted, as was described above, the VI Study is unreliable, flawed and misleading and cannot establish the real-world clinical performance of the VI Syringe. The VI Study does not and cannot accurately and reliably reflect the test's actual clinical performance in the real-world settings. As discussed below, Defendants' false and misleading marketing statements deceptively and repeatedly omit reference to confidence interval, sample size, or any other contextual information that are needed to appropriately interpret the Blood Culture contamination (BCC) reduction results reported in the VI Study.

109. The above are representative (not exhaustive) examples of the flaws, limitations, and unreliability of the VI Study. Being flawed, limited, and unreliable

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in these ways, the VI Study does not and cannot establish Defendants' BCC reduction claims for the VI Syringe.

110. Relying on the VI Study, Defendants have flooded the marketplace—throughout the United States—with false, misleading, and deceptive claims about the clinical performance of the VI Syringe. These claims are not established by the VI Study or any other published study on the VI Syringe. Defendants continue to repeat and spread their false and misleading claims, which deceive the medical community about the clinical performance of the VI Study.

111. On information and belief, Defendants have disseminated these claims and other similarly false and misleading claims to, among others, physicians, payors, investors, members of the media, and other stakeholders including government agencies, health systems, KOLs, advocacy groups, medical societies, task forces, and the medical community at-large, on public-facing websites, press releases, and social media accounts, and also through direct communications with those identified above, including emails, phone calls, videoconferences, and in-person conversations.

112. Defendants' false and misleading statements, including without limitation those outlined below, whether considered alone or together, have at least a tendency to deceive a substantial portion of the intended audience (*e.g.*, healthcare workers, payors, investors, and other stakeholders in the BCC/CLABSI reduction and hemolysis reduction spaces).

113. Defendants' false and misleading statements regarding the performance of the VI Syringe have been disseminated in interstate commerce and have affected, or will affect, sales of the VI Syringe and/or the Kurin Lock® family of products that are made in interstate commerce.

114. On information and belief, Defendants have repeated the same false and misleading claims, or other similarly false and misleading claims, through other sources, including direct communications such as emails, phone calls, videoconferences, and in-person conversations.

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115. Defendants' false and misleading statements relate to the VI Syringe, which includes test kits that have been, and will be, shipped by Defendants' across the United States, as well as test results that have been, and will be, provided by Defendants' to healthcare providers across the United States. As explained above, in connection with Defendants' false and misleading acts, Defendants' have introduced the VI Syringe into interstate commerce in connection with testing, and on information and belief, for other purposes such as for demonstrations, presentations, and developing business relationships, such as VI's relationship with ICU who will distribute the VI Syringe across the United States for large-scale commercial use. Moreover, as discussed in more detail, *infra*, Defendants' statements have affected, or will affect, sales of the Kurin Lock® family of products, which are sold throughout the United States.

116. Defendants' false and misleading statements about the VI Syringe are material. As explained above, these statements misrepresent the study results and the clinical performance (including relative to the VI Syringe) to deceive those who might order, or request to order, the VI Syringe for BCC/CLABSI and hemolysis reductions. Defendants' statements (*e.g.*, regarding BCC/CLABSI and hemolysis reductions) are of the type that, if taken as true, provide a false representation of VI Study characteristics, uses, benefits, quality, and/or facts that are likely to influence purchasing and screening decisions, thus, they are material misrepresentations.

117. For instance, a prospective healthcare provider may view Defendants' promotion of the 99.9% Claim for the VI Syringe, and then compare it to Kurin's reported more than 80% BCC reduction (based on multiple, peer reviewed, third-party studies), and elect to use the VI Syringe instead of the Kurin Lock® family of products. Such misleading statements may reasonably be expected to disincentivize patients to use the Kurin Lock® family of products and instead incentivize them to use the VI Syringe under the misunderstanding that VI Syringe has comparably higher BCC reduction than the Kurin Lock® family of products.

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118. Defendants knowingly and willfully communicate their misrepresentations to the public and other stakeholders, including potential customers of both the VI Syringe and the Kurin Lock® family of products.

119. Defendants' commercial advertising and promotions have had their intended effect. Since Defendants' misinformation campaign began, it is evident that Defendants' false and misleading statements have already begun to influence the market to reach inaccurate conclusions—including that the VI Syringe has demonstrated superior (or at least equivalent) performance than Kurin's products, with a higher BCC reduction rate including Defendants' 99.9% Claim. For example, Defendants claim that the VI Syringe is "evaluated and endorsed by ANTT to reduce contamination and ensure best practice," as shown in Exhibit 1. As shown in Exhibit 1, Defendants represent that "ANTT stands for Aseptic Non Touch Technique. It is an evidence-based standardized approach to aseptic technique developed by the Aseptic Safety And Practice (ASAP) company." As shown in Exhibit 1, Defendants provide a link to the ANTT website at https://www.antt.org/, a true and correct copy of which is attached as **Exhibit 3**. By cloaking the VI Syringe in the endorsement by the ANTT, through false and misleading claims, Defendants are trying to influence healthcare purchasers with ANTT as a purported opinion leader.

120. Defendants' false and misleading statements have already had their intended effect. For example, Defendants' false and misleading statements have influenced Becker's Hospital Review, a true and correct copy of which is attached as **Exhibit 39**, to state that "The ByPass Syringe is commonly used by hospitals for blood diversion, to help reduce false positive blood cultures," and that hospitals "also commonly leverage the ByPass Syringe for its Velocity Reduction Technology™ to help reduce hemolysis."

121. Each false and misleading statement Defendants have made regarding the VI Syringe has deceived, and further has the tendency to deceive, a substantial portion of the intended audience, including doctors, payors, investors, and other

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stakeholders, including government agencies, health systems, KOLs, advocacy groups, and medical societies, and task forces. Defendants' efforts to falsely elevate the performance of the VI Syringe relative to competitor products (such as the Kurin Lock® family of products) have misled, and are likely to mislead physicians, clinicians, healthcare institutions, potential customers, payors, investors, and other stakeholders, and is expected to cause them to view the Kurin Lock® family of products as less effective than the VI Syringe, and to order the VI Syringe rather than the Kurin Lock® family of products.

122. If Defendants are not stopped, Defendants' campaign of deceptive statements will cause further injury to Kurin, including irreparable harm to Kurin's business and reputation and lost sales of the Kurin Lock® family of products. Defendants' unsubstantiated marketing claims threaten the reputation of the Kurin Lock® family of products and the reputation of Kurin itself, eroding Kurin's goodwill among its customers and threaten the loss of orders of the Kurin Lock® family of products.

123. Defendants' statements are also injurious because they have generated confusion and doubt about the quality and performance of the Kurin Lock® family of products relative to the VI Syringe, which is expected to depress customer demand for the Kurin Lock® family of products and lead to declining sales. By misleading physicians, investors, payors, and other stakeholders into believing that Defendants' reports about the VI Syringe performance are fully supported and impliedly superior to the Kurin Lock® family of products, Defendants, on information and belief, have caused and will continue to cause patients to forego and miss out on the benefits of the Kurin Lock® family of products under a false impression about the performance of a competing test.

124. To the extent physicians, healthcare workers, payors, investors, and other stakeholders are duped into believing Defendants' false and misleading statements and choose the VI Syringe instead of the Kurin Lock® family of products,

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Defendants will have interfered with business relationships that Kurin reasonably expects to support.

125. For at least these reasons, Defendants' unfair and unlawful use of false advertising interferes with Kurin's reputation and reasonable expectation of business relationships, thereby further harming Kurin.

126. As a direct and proximate result of the wrongful acts of Defendants alleged above, Kurin has suffered, and will in the future suffer, substantial damage to its business, including through loss of business relationships, customers, and sales, and associated revenues, together with harm to its reputation and goodwill. If Defendants are successful, patients and hospitals will be harmed, it will divert sales from Kurin to itself under false premises, sales which will be difficult if not impossible to recapture so long as Defendants are spreading false and misleading information about Defendants' VI Syringes.

127. Only by stopping Defendants' false advertising campaign, and correcting the misinformation already taking hold in the field, can these harms be averted.

COUNT I: FALSE ADVERTISING

IN VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125)

128. Kurin realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

129. Defendants have made and continues to make false and misleading statements in interstate commerce, including Defendants' False and Misleading Statements, including in their advertising, their promotional materials to healthcare professionals and members of the public, and statements to others about the performance and quality of the VI Syringe.

130. Defendants' false and misleading statements have and will continue to affect goods that have travelled and will travel in interstate commerce, including the VI Syringe and the Kurin Lock® family of products.

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131. Defendants' false and misleading statements are designed to mislead healthcare professionals, patients, and others into believing that the VI Syringe has and/or will have clinical performance that the VI Study cannot establish or has not established, that the VI Syringe is superior to competing products such as Kurin's Kurin Lock® family of products despite the lack of any support for Defendants' False and Misleading Claims, and ultimately that the VI Syringe has performed and/or will perform better than it actually does. Defendants' false and misleading statements are further designed to deceive and mislead healthcare professionals, patients, and others into believing that there is reliable and representative study data supporting their performance claims when in fact the data is insufficient and/or unreliable to support those claims.

132. Defendants' statements are literally false and/or misleading commercial speech in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

133. Defendants made these false and misleading statements in interstate commerce that have affected, or will affect, sales of the VI Syringe and/or the Kurin Lock® family of products that are made in interstate commerce. Defendants made these false and misleading statements in the context of commercial advertising or promotion as they were made for the purpose of influencing healthcare providers, patients, and others to recommend, use, purchase, and otherwise prefer the VI Syringe over competing products, such as Kurin's Kurin Lock® family of products.

134. Defendants intended for these false and misleading statements to deceive healthcare providers, patients, and others about the quality and performance of their VI Syringe, to Kurin's detriment.

135. Defendants' false and misleading statements are material and likely to influence the decisions of healthcare providers, patients, and others, including but not limited to the decision to purchase and/or use the VI Syringe instead of competing products, such as the Kurin Lock® family of products.

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136. Defendants' false and misleading statements are material and likely to influence healthcare providers, patients, and others to choose the VI Syringe over the Kurin Lock® family of products.

137. Defendants made these false and misleading statements knowingly and willfully.

138. Kurin has suffered, and will in the future suffer, significant harm as a result of Defendants' false and misleading statements, including diminished reputation, loss of goodwill, lost sales, loss of future revenues, loss of investments, loss of customers, and confusion about comparative performance of the VI Syringe relative to the Kurin Lock® family of products that needs to be corrected.

139. Defendants' conduct violates Section 43(a) of the Lanham Act in a manner that harms Kurin. Kurin is therefore entitled to all relief available under the Lanham Act, 15 U.S.C. § 1117(a), including but not limited to disgorgement of Defendants' profits, actual damages, and attorneys' fees and costs.

COUNT II: FALSE ADVERTISING IN VIOLATION OF CAL. BUS. & PROF. CODE § 17500 *ET SEQ.*

140. Kurin realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

141. Kurin brings this counterclaim pursuant to Cal. Bus. & Pro. Code § 17535 in an individual capacity and not on behalf of the general public.

142. Defendants have made false and misleading statements, including those described as the False and Misleading Claims, that constitute deceptive trade practices in violation of the California Unfair Practices Act, beginning at Section 17000 of the California Business & Professions Code.

143. Cal. Bus. & Prof. Code § 17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or to perform services, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate before the public, through the use

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of untrue and misleading statements that were known, or should have been known with the exercise of reasonable care, to be untrue and misleading.

144. Cal. Bus. & Prof. Code § 17508 provides, in pertaining part, "(a) it shall be unlawful for any person doing business in California and advertising to consumers in California to make any false or misleading advertising claim, including claims that (1) purport to be based on factual, objective, or clinical evidence, (2) compare the product's effectiveness or safety to that of other brands or products, or (3) purport to be based on any fact."

145. Defendants have violated Cal. Bus. & Prof. Code §§ 17500 and 17508 by making untrue and misleading statements, including Defendants' False and Misleading Statements, including but not limited to written promotional materials to healthcare professionals, insurance providers, patients, and others, about the performance and quality of their VI Syringe. Defendants' untrue and misleading statements are designed to—and likely will continue to—mislead healthcare professionals, patients, and others into believing that the VI Syringe performs better than it actually does, and that it is superior to the Kurin Lock® family of products.

146. Defendants' false and misleading statements purport (but fail) to be based on factual, objective, or clinical evidence. The false and misleading statements improperly make the False and Misleading Claims and those false and misleading statements likely will influence healthcare providers, patients, and the general public to choose the VI Syringe over the Kurin Lock® family of products. Defendants' false and misleading statements further purport (but fail) to be based on facts; in truth they are distortions of fact and context-bereft statements that are false or wholly misleading.

147. Defendants' false and misleading statements represent that the VI Syringe has uses and benefits that it does not have.

148. Defendants' false and misleading statements represent that the VI Syringe is of a higher standard, quality, or grade than it actually is.

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149. Defendants' false and misleading statements implicitly disparage Kurin and the Kurin Lock® family of products by false and misleading statements of fact concerning the VI Syringe's clinical performance, including in comparison to other BCC reduction products on the market, including the Kurin Lock® family of products.

150. Defendants' false and misleading statements advertise goods and services with the intent not to sell them as advertised.

151. Defendants' false and misleading statements create a likelihood of confusion or misunderstanding, and represents that the VI Syringe is of a particular standard, quality, or grade when it is not.

152. Defendants' made their false and misleading statements knowingly or recklessly.

153. As a result of Defendants' violations, Kurin has suffered—and, unless Defendants' conduct is enjoined by this Court, will likely continue to suffer—irreparable injury, including, but not limited to, the loss of revenue, goodwill, and diminished reputation.

154. Defendants' conduct has caused Kurin damage in an amount to be determined at trial. Kurin is entitled to damages to compensate for all actual harm caused by Defendants' conduct.

155. Pursuant to Cal. Bus. & Prof. Code § 17535, Kurin seeks an order of this Court (1) compelling Defendants to provide restitution, and to disgorge monies to which Kurin is entitled but were instead collected and realized by Defendants as a result of their false and misleading statements, and (2) providing injunctive relief enjoining Defendants from making such false and misleading statements.

COUNT III: UNLAWFUL TRADE PRACTICE IN VIOLATION OF CAL. BUS. & PROF. CODE § 17200 *ET SEQ.* BY DEFENDANTS

156. Kurin incorporates by reference all allegations set forth above as if fully set forth herein.

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157. Under Cal. Bus. & Prof. Code § 17200, unfair competition is defined as and includes any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising. This includes, but is not limited to, any conduct or statement related to the operation of a business that is deceptive, untrue, misleading, and/or fraudulent.

158. Defendants have violated Cal. Bus. & Prof. Code § 17200 by making untrue and misleading statements, including Defendants' False and Misleading Statements, including but not limited to press releases, at least one public presentation, and written promotional materials to healthcare professionals, insurance providers, patients, and others, about the performance and quality of their VI Syringe. Further, Defendants' conduct constitutes a violation of the Lanham Act, and thus their unlawful business conduct is separately actionable as a violation of Cal. Bus. & Prof. Code § 17200 *et seq.* Defendants' conduct is also independently unlawful and unfair, in violation of these provisions. Defendants have also violated Cal. Bus. & Prof. Code § 17200 by engaging in fraudulent business acts or practices that defraud consumers and potential consumers of BCC/CLABSI and hemolysis reductions devices into believing that the VI Syringe is more effective than it actually is based on manipulated methodology and data that Defendants rely on to market the VI Syringe.

159. As a result of Defendants violations, Kurin has suffered—and, unless Defendants' False and Misleading Claims are enjoined by this Court, will likely continue to suffer—irreparable injury, including, but not limited to, goodwill and diminished reputation for which Kurin has no adequate remedy at law.

160. Defendants' conduct has caused Kurin damage in an amount to be determined at trial. Kurin is entitled to damages to compensate for all actual harm caused by Defendants' conduct.

161. Defendants have been unjustly enriched from their conduct. Pursuant to Cal. Bus. & Prof. Code § 17203, Kurin seeks an order of this Court compelling

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Defendants to provide restitution, and to disgorge monies to which Kurin is entitled but were instead collected and realized by Defendants as a result of their false and misleading statements and injunctive relief enjoining Defendants from making such false and misleading statements.

162. Kurin is further entitled to recover costs and attorneys' fees pursuant to California Unfair Competition Law.

COUNT IV: UNFAIR COMPETITION UNDER COMMON LAW

163. Kurin realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

164. Defendants' false and misleading statements, including Defendants' False and Misleading Statements, including in their marketing, advertising, and promotional activities constitute unfair competition that have deceived, or are likely to deceive, customers and has caused, or is likely to cause, injury to Kurin.

165. Defendants know, or in the exercise of reasonable discretion should know, that their marketing program deceives healthcare providers, patients, and the general public about the nature, characteristics, and qualities of the VI Syringe in comparison, connection, or association with Kurin's Kurin Lock® family of products.

166. Defendants' false and misleading statements were made in interstate commerce that have affected, or will affect, sales of the VI Syringe and/or the Kurin Lock® family of products that are made in interstate commerce. Defendants made these false and misleading statements in the context of commercial advertising or promotion, as they were made for the purpose of influencing patients, healthcare providers, and others to use Defendants' VI Syringe instead of Kurin's Kurin Lock® family of products when using BCC/CLABSI and hemolysis reduction products, as well as to harm Kurin's reputation and business prospects in the marketplace.

167. Defendants made their false and misleading statements knowingly or recklessly to healthcare providers, patients, and others.

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168. Defendants' false and misleading statements likely have deceived and, unless stopped, will continue to deceive, healthcare providers, patients, and others about the performance of the VI Syringe.

169. Defendants' false and misleading statements have caused and are likely to cause substantial harm to Kurin in the marketplace, including lost business and loss of goodwill and reputation.

170. Kurin is entitled to damages for Defendants' unfair competition, an accounting of profits made on sales of Defendants' VI Syringe, and recovery of Kurin's costs of this action.

171. Defendants' actions have been willful and have been undertaken with the purpose of deceiving consumers. Thus, Kurin is entitled to an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Kurin respectfully requests the following relief:

172. A judgment that Defendants have violated 15 U.S.C. § 1125(a), including in connection with their false and misleading commercial promotion of the VI Syringe;

173. A judgment that Defendants have violated the Cal. Bus. & Prof. Code § 17500 *et seq.*, including in connection with their deceptive activities concerning the VI Syringe;

174. A judgment that Defendants have violated the Cal. Bus. & Prof. Code § 17200 *et seq.*, including in connection with their deceptive activities concerning the VI Syringe;

175. A judgment that Defendants have engaged in unfair competition under California law, including in connection with their deceptive activities concerning the VI Syringe;

176. An injunction enjoining Defendants and their officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all

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others acting on behalf of or in active concert or participation therewith, from making false and misleading statements about their VI Syringe;

177. An order requiring Defendants to take all necessary corrective measures to correct the false and misleading impressions created among healthcare professionals and others by their false and misleading statements;

178. An award of damages sufficient to compensate Kurin's for Defendants violations of 15 U.S.C. § 1125(a), Cal. Bus. & Prof. Code § 17500 *et seq.*, Cal. Bus. & Prof. Code § 17200 *et seq.*, and/or unfair competition under California law, including but not limited to Kurin's lost business and profit, harm to Kurin's goodwill and reputation, and Defendants' ill-gotten and unjustly derived revenues;

179. An award of punitive and exemplary damages for Defendants' violations of 15 U.S.C. § 1125(a), Cal. Bus. & Prof. Code § 17500 *et seq.*, Cal. Bus. & Prof. Code § 17200 *et seq.*, and/or unfair competition under California law;

180. An award of attorneys' fees Kurin incurred for Defendants' violations of 15 U.S.C. § 1125(a), Cal. Bus. & Prof. Code § 17500 *et seq.*, Cal. Bus. & Prof. Code § 17200 *et seq.*, and/or unfair competition under California law;

181. Costs and expenses that Kurin incurred in this action, including expert witness fees;

182. An award of prejudgment and post-judgment interest;

183. Statutory damages, including multipliers and equitable enhancements, and

184. Such other and further relief as the Court may deem just and proper.

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Dated: March 15, 2024

SNELL & WILMER L.L.P.

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Kurin respectfully demands a trial by jury on all triable issues.

Dated: March 15, 2024

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By: *Christopher D. Bright*
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